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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,141	02/18/2004	Carl W. Hastings	30105/32001A	3364

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
12/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,141	HASTINGS ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-27* is/are pending in the application.

4a) Of the above claim(s) *25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed May 19, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 11, 13, 14 and 20 under 35 U.S.C. 112, second paragraph is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 11-14 under 35 U.S.C. 102(e) as being anticipated by Gardiner (U.S.Patent No. 6,136,339) is hereby expressly withdrawn in view of Applicants' argument.

The rejection of claims 15-24 under 35 U.S.C. 103(a) as being unpatentable over Gardiner (U.S.Patent No. 6,136,339)(Gardiner'339) in view of Hastings et al. (U.S.Patent No. 6,224,871B1), Ribnicky et al. (U.S.Patent No. 6,893,627 B2), Brantman (U.S.Patent No. 4,687,782), Michnowski (U.S.Patent No. 4,832,971), Gardiner (U.S.Patent No. 5,817,329) (Gardiner '329), Riley (U.S.Patent No. 5,976,568) and Ecker (U.S.Patent No. 3,894,148) is hereby expressly withdrawn in view of Applicants' argument.

Applicants' arguments with respect to claims 11-24 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaddurah-Daouk et al. (WO 97/13507A1) and Wessel et al. (U.S.Patent No. 5,948,810).

Instant claims are drawn to a food supplement, comprising lipoic acid and creatine.

Kaddurah-Daouk et al. teach that creatine is useful for the treatment of a glucose metabolic disorder such as diabetes mellitus. (abstract, page 1, first sentence, page 10 Table 1, first compound, claims 1-10).

Wessel et al. teach that alpha lipoic acid is useful for the treatment of diabetes mellitus of type I and II, compensated and decompensated insulin resistance. (abstract, claims).

The claims differ from the cited references in claiming combination of creatine and alpha lipoic acid in a single composition such as a food supplement for the treatment of diabetes. To employ combinations of creatine and alpha lipoic acid in a single composition to treat diabetes mellitus would have been obvious because all the components are well known individually for treating diabetic conditions. It would be expected that the combination of components in a single composition would treat diabetic conditions as well. One of ordinary skill in the art would have combined the antidiabetic agents by known methods and that in combination; each element merely would have performed the same antidiabetic activity as it did separately. The convenience of putting the compounds having the same antidiabetic activity (lipoic acid and creatine) together with a carrier/excipient in one dosage form, though perhaps a matter of great convenience does not produce a "new" or "different" function and to those skilled in the art, the use of the old elements in combination would have been obvious. The motivation for combining the components flows from their individually

known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). As stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

Therefore, it would have been *prima facie* obvious to combine creatine and alpha lipoic acid conjointly in a single composition to treat diabetes mellitus.

With regard to the recitation of "a food supplement", this recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaddurah-Daouk et al. (WO 97/13507A1) and Wessel et al. (U.S.Patent No. 5,948,810) as applied to claims 11-13 and further in view of Smith et al. (U.S.Patent No. 5,039,704).

The teachings of Kaddurah-Daouk et al. and Wessel et al. as applied as before.

Neither Kaddurah-Daouk et al. nor Wessel et al. teaches employment of glutamine.

Smith et al. teach that a catabolic dysfunction is a condition occurring during or following uncontrolled diabetes due to increased demand for glutamine. Smith et al. teach that the catabolic dysfunction can be treated by administering a therapeutically effective amount of glutamine.

To incorporate glutamine in the diabetic composition comprising alpha-lipoic acid and creatine as modified by Kaddurah-Daouk et al. and Wessel et al. is obvious in view of Smith et al. who teach that glutamine is therapeutically effective for a catabolic dysfunction related to diabetes. One would have been motivated to make such a modification in order to avoid the occurrence of catabolic dysfunction in a patient suffering from diabetes during or following uncontrolled diabetic episodes. There is a reasonable expectation of successfully formulating an antidiabetic composition that additionally prevents a condition (catabolic dysfunction) that can occur during or following uncontrolled diabetes. The salts (e.g. monohydrate) of active agents (creatine) to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

Claims 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner (U.S.Patent No. 5,817,329) of record, Brantman (U.S.Patent No. 4,687,782) of record, Michnowski (U.S.Patent No. 4,832,971) of record, Riley (U.S.Patent No.

5,976,568) of record, Ecker (U.S.Patent No. 3,894,148) of record, Product Alert (1996), Majeed et al. (U.S.Patent No. 5,536,506) and Pariza et al. (U.S.Patent No. 5,856,149).

Gardiner (Gardiner '329) teaches a composition useful as a **diet supplements** for athletes and body builders comprising **carnitine**, **ornithine alpha-ketoglutarate**, **l-glutamine**, **l-leucine**, **l-isoleucine**, **l-glycine** and **l-valine as a creatine synthesizer**. (abstract, column 4, line 24, claims 6-12). Gardiner teaches that ornithine alpha-ketoglutarate prevents muscle breakdown. (column 5, lines 13-15). Gardiner teaches that **alanine** and **glutamine** is a known fuel of the muscle and brain. (column 2, lines 45-65).

Gardiner does not teach the fructose, soy protein isolate, grape seed extract, coenzyme Q10, *piper nigrum* extract, alpha lipoic acid and l-lysine, conjugated linoleic acid, phosphatidylserine/phosphatidylcholine complex, medium chain triglycerides, lecithin and their specific amounts, and the daily serving amounts.

Ecker teaches the process for enhancing the energy metabolism and physical endurance of athletes comprising administering fructose. Ecker teaches that **fructose** is **an energy food** and can be utilized by the cells of the body to derive energy. Ecker teaches that various advantages of utilization of fructose versus glucose. (abstract, column 3, lines 21-67, formulations on column 5 and 6).

Michnowski teaches a **nutritional athletic bar** comprising **soy proteins, such as isolates or concentrates and fructose granules**. (title, abstract, column 5, lines 49-67, column 6, lines 10-20). Michnowski teaches that such nutritional bars are

suitable as snacks for hikers, skiers, mountain climbers and athletes. (column 7, lines 65-68).

Brantman teaches a combinations of **amino acids (carnitine, glutamine, isoleucine, leucine and valine) and soy protein, medium-chain triglycerides** for **supplementing the diet** of an athlete. (abstract, Example I, claim 1).

Riley teaches multivitamin and mineral **supplementation** comprising **Coenzyme Q-10, alpha lipoic acid,** and **grape seed extract**. (abstract, column 20-21, table).

Product Alert (1996) teaches **a nutrient supplement** comprising **phosphotidyl serine together with phosphatidylcholine**.

Majeed et al. teach that the composition comprising **Piper nigrum** as an essential ingredient is useful for improving the bioavailability of certain nutritional compound. (abstract, column 3, lines 45-50, column 4, lines 19-21).

Pariza et al. teach that **conjugated linoleic acid (CLA)** occurs naturally in a wide **variety of food** and it is now recognized as **a nutritional supplement**. (column 1, lines 23-24, 30-31). Pariza et al. teach that stabilizing emulsifier such as **lecithin** can be added to the CLA composition. (column 6, lines 60-64).

It would have been obvious to one of ordinary skill in the art to modify Gardiner's nutritional food supplement and incorporate other agents such as fructose, soy protein isolate, l-carnitine, grape seed extract, coenzyme Q10, piper nigrum extract, alpha lipoic acid, l-leucine, l-alanine and glycine, l-arginine, l-lysine, conjugated linoleic acid, phosphatidylserine/phosphatidylcholine complex, ornithine alpha-ketoglutarate, medium chain triglycerides and lecithin because all these agents are useful and effective for

providing diet supplement and suitable for nutritional diet as taught by individual references. One of ordinary skill in the art would have combined the nutritional supplements above by known methods and that in combination; each element merely would have performed the nutritional supplement as it did separately. The convenience of putting the compounds having the same nutritional dietary supplements together with a carrier/excipient in one dosage form, though perhaps a matter of great convenience does not produce a "new" or "different" function and to those skilled in the art, the use of the old elements in combination would have been obvious. Therefore, it would be expected that the combination of components would be beneficial in supplementing nutrition, particularly including athletes who needs various nutritional supplement for enhancing energy as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). With respect to the claimed concentrations of the active agents, concentration limitations are obvious absent evidence to the contrary. Please see Akzo v. E. I. Du Point de Nemours, 1 USPQ 2d 1704 (Fed. Cir. 1987). Moreover, in view of the prior art, one of ordinary skill in the art would optimize dosage amounts so as to provide optimum dietary/nutritional benefits. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
October 20, 2008